

EXHIBIT A

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TORPHARM, INC.,)
)
Plaintiff,) Docket No. CA 03-2401
)
v.)
)
FDA,) Washington, D.C.
) Friday, January 2, 2004
Defendant.)

TRANSCRIPT OF PRELIMINARY INJUNCTION HEARING
BEFORE THE HONORABLE RICHARD W. ROBERTS
UNITED STATES DISTRICT JUDGE

APPEARANCES:

For the Plaintiff:

OLSSON, FRANK AND WEEDA
Arthur Y. Tsien, Esq.
1400 Sixteenth Street, N.W.
Washington, D.C. 20036-2220
202.518.6318
LORD, BISSELL & BROOK
Deanne M. Mazzochi, Esq.
Hugh S. Balsam, Esq.
115 S. LaSalle Street
Chicago, IL 60603-3901
312.443.0700

For the Defendant:

UNITED STATES DEPARTMENT OF JUSTICE
Douglas Stearn, Trial Attorney
P.O. Box 386
Washington, D.C. 20044
202.307.0061

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Marc L. Caden, Associate Chief Counsel
5600 Fishers Lane, GCF-1
Rockville, MD 20857
301.827.7141
Scott L. Wallace, RDR, CRR
Official Court Reporter

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<p style="text-align: right;">Page 2</p> <p>APPEARANCES: Cont.</p> <p>Intervening Defendant: FROMMER, LAWRENCE & HAUG, LLP Charles J. Raubicheck, Esq. (Alphapharm) 745 Fifth Avenue New York, NY 10151 212.588.0800</p> <p>Court Reporter: Scott L. Wallace, RDR, CRR Official Court Reporter Room 6814, U.S. Courthouse Washington, D.C. 20001 202.326.0566</p> <p>Proceedings reported by machine shorthand, transcript produced by computer-aided transcription</p> <p style="text-align: right;">Scott L. Wallace, RDR, CRR Official Court Reporter</p>	<p style="text-align: right;">Page 4</p> <p>1 MS. MAZZOCHI: And would you like me to proceed or do you 2 need to have defense — 3 THE COURT: Well, you can introduce yourself just for the 4 record. 5 MS. MAZZOCHI: That's fine. My name is Deanne Mazzochi 6 and I'm an attorney with Lord, Bissell & Brook in Chicago, acting 7 on behalf of Torpharm. 8 THE COURT: Very well. 9 MR. STEARN: Good afternoon, Your Honor. My name is 10 Douglas Stearn. I'm here with the Department of Justice on 11 behalf of the federal defendants, the Food and Drug 12 Administration, Secretary Thompson and Commissioner McClellan. 13 With me is Marc Caden with the Office of Chief Counsel at 14 FDA. 15 THE COURT: All right, good afternoon. 16 MR. RAUBICHECK: And excuse me, Your Honor. My name is 17 Charles Raubicheck. I'm with the firm of Frommer, Lawrence & 18 Haug, representing the intervening defendant, Alphapharm, Pty, 19 Limited. 20 THE COURT: All right. Good afternoon to all of you. 21 I want to take up first the suggestion in the papers that 22 this matter be treated as summary judgment papers or the 23 preliminary injunction hearing be consolidated on the merits 24 under Rule 65. 25 I've looked at the papers and I have not found any genuine</p>
<p style="text-align: right;">Page 3</p> <p>1 PROCEEDINGS</p> <p>2 THE DEPUTY CLERK: This is civil action 03-2401, Torpharm, 3 Inc. versus FDA; intervening defendant, Alphapharm.</p> <p>4 Counsel, would you kindly step up to the podium and 5 introduce yourself to the judge.</p> <p>6 MR. TSIEN: Good afternoon, Your Honor. Arthur Tsien from 7 Olsson, Frank and Weeda for Plaintiff Torpharm.</p> <p>8 Torpharm would like Deanne Mazzochi from Lord, Bissell & 9 Brook in Chicago to represent it here today. Your Honor granted 10 her motion to appear pro hac vice on a provisional basis 11 Wednesday. We cured a defect by submitting a supplemental 12 declaration Wednesday.</p> <p>13 THE COURT: All right. I'm not sure that I've seen it, 14 but I will trust that you added the number of times, I think, 15 that was missing?</p> <p>16 MR. TSIEN: I would be pleased to hand up a copy, Your 17 Honor.</p> <p>18 THE COURT: All right. Well, just tell me what the number 19 was. Was there a number?</p> <p>20 MS. MAZZOCHI: It was zero, in fact.</p> <p>21 THE COURT: Zero times. Well, I will convert my 22 provisional ruling to a final ruling. You are admitted pro hac 23 vice and welcome to the Court.</p> <p>24 MS. MAZZOCHI: Thank you, Your Honor.</p> <p>25 THE COURT: All right.</p>	<p style="text-align: right;">Page 5</p> <p>1 dispute in your papers about material facts, so I do propose to 2 proceed that way unless there is some objection to that. 3 Now, with respect to argument, what if I give each side 4 roughly a half hour? Now, maybe the FDA and Alphapharm might 5 want to divide that up any way you want to; Torpharm, if you want 6 to reserve some of your time for rebuttal, you can do that. 7 But had you all discussed some alternative way of 8 proceeding or some alternative schedule? If not, why don't we 9 just proceed in that fashion and invite Torpharm to go first.</p> <p>10 MS. MAZZOCHI: Thank you, Your Honor. If I may, I would 11 like to reserve approximately ten minutes of rebuttal time.</p> <p>12 THE COURT: All right.</p> <p>13 MS. MAZZOCHI: And just to begin, I would like to thank 14 the Court very much for taking the time to hear us today. We 15 understand with the holidays and the urgency involved, that 16 additional efforts are required.</p> <p>17 As this Court is aware, this case involves 180-day 18 exclusivity periods under the Hatch-Waxman Act, which the D.C. 19 Circuit has recognized in <i>Mova v. Shalala</i> is a very powerful 20 incentive for generic companies to invite patent challenges years 21 before market entry is possible.</p> <p>22 There's no dispute here amongst the parties that Torpharm 23 is, in fact, the first ANDA applicant to file an ANDA with a 24 paragraph IV certification.</p> <p>25 THE COURT REPORTER: Slow down just a little bit.</p>

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<p style="text-align: right;">Page 6</p> <p>1 MS. MAZZOCHI: Sure. I apologize. 2 Torpharm is the first ANDA applicant to submit to FDA an 3 ANDA which contained a paragraph IV certification for the patent 4 that was then listed in the FDA publication known as the Orange 5 Book, U.S. patent number 4,721,723. 6 And our understanding is that as of tomorrow, FDA is 7 planning to deny Torpharm its exclusivity rights as a result of 8 that filing, and that — 9 THE COURT: You mean sole exclusivity rights? 10 MS. MAZZOCHI: Sole exclusivity rights. 11 And that FDA is in fact planning on awarding a shared 12 exclusivity right to Alphapharm. We believe that this denial of 13 Torpharm's ability to fully exploit its 180-day exclusivity 14 period represents arbitrary and capricious agency action for 15 several reasons. 16 First, we believe that the statute on its face creates a 17 sole exclusivity right by requiring FDA to delay approval of 18 rival ANDAs until the expiration of 180 days after certain 19 triggering events in the statute, which everyone agrees here was 20 Torpharm's first commercial marketing date, which was 21 September 8th of 2003. 22 180 days from that period would be approximately March 6th 23 of 2004. 24 THE COURT: Did you say that was the first commercial 25 marketing date or the date on which the secretary is notified of</p>	<p style="text-align: right;">Page 8</p> <p>1 way in which it can reconcile conducting a patent-by-patent 2 approach to exclusivity with the statute, we believe that, at the 3 very least, ensuring that the first 180-day exclusivity period is 4 not devalued by nature of having to be shared amongst one or, I 5 believe here for Paroxetine, there are now over ten ANDA 6 applicants who have gotten ANDA applications on file, the 7 cascading approach would allow you to, at the very least, keep 8 the first ANDA applicant's exclusivity period fully in place and 9 would allow the first applicant to fully enjoy the fruits of 10 their litigation labors, if you will. 11 And if FDA truly believes that there are policy advantages 12 to taking the patent-by-patent based approach, which would 13 encourage other generic applicants to challenge late-listed 14 patents, we believe that having the cascading approach would, 15 again, ensure that you've got some type of incentive that is 16 fixed, that is readily discernible and that can actually be 17 counted on in terms of proceeding forward with litigation and, 18 you know, up front making the decision as to whether it's even 19 worth the time to submit a paragraph IV certification in the 20 first instance. 21 THE COURT: Well, would you concede that I can't even 22 reach the question about cascading exclusivity until and unless I 23 decide that the statute is ambiguous? And if there is some 24 ambiguity, then we have to march into whether the FDA's 25 interpretation of it was permissible and reasonable?</p>
<p style="text-align: right;">Page 7</p> <p>1 the first commercial marketing? 2 MS. MAZZOCHI: It was — we believe that the notice did, 3 in fact, occur simultaneously, so there may be a day or two 4 leeway one way or the other. But I believe the parties are in 5 agreement that the end of the exclusivity period comes at about 6 March 6th of 2004. 7 Nowhere in the statute does it set forth any type of 8 regime where exclusivity can be shared simultaneously amongst 9 ANDA applicants. FDA has invented this concept in a series of 10 ad hoc letter rulings against a background of administrative 11 positions which have involved several flip flops as to what FDA 12 considers to be an appropriate way to award and consider who has 13 entitlement to 180-day exclusivity periods. 14 THE COURT: Well, forgive me for interrupting. Can I ask 15 you two questions on that argument? 16 MS. MAZZOCHI: Sure. 17 THE COURT: How does that argument support your advancing 18 the argument that this cascading or rolling exclusivity may be an 19 appropriate interpretation of the statute where the statute has 20 no such reference to that either? 21 MS. MAZZOCHI: We — FDA has taken the position that the 22 statute authorizes it to analyze exclusivity on a, quote/unquote, 23 patent-by-patent basis. We obviously believe that the 24 one-first-applicant approach is the correct approach. However, 25 if there is some perception that FDA believes there needs to be a</p>	<p style="text-align: right;">Page 9</p> <p>1 MS. MAZZOCHI: I think that — Torpharm believes that what 2 the statute requires is that there be one ANDA applicant, notably 3 the first filer, who fully enjoys their 180-day exclusivity 4 period. 5 As to which approach is deemed the most proper one by the 6 Court, we are willing to leave that to the Court to decide. We 7 believe that the first applicant approach is the correct one, but 8 under either approach, Torpharm still comes out of this with its 9 180-day exclusivity period intact and FDA still cannot approve 10 Alphapharm's ANDA until after — on or after about March 6th, 11 2004. 12 THE COURT: Well, that answers the result. I was asking 13 about process. I take it you don't disagree that, absent the 14 language in the statute about cascading, I'd have to find some 15 ambiguity that would allow me to go in and then determine whether 16 the FDA's interpretation was permissible or reasonable? 17 MS. MAZZOCHI: I believe that the statute discusses having 18 a previous application and we believe that that previous 19 application refers to a first ANDA applicant. You can still have 20 a first ANDA applicant under the cascading approach as well. 21 The question is whether you're going to give — you're 22 going to consider subsequent applicants who are filing a newly 23 listed patent to constitute a new ANDA application that has a 24 paragraph IV certification for which there was no prior paragraph 25 IV certification as to that same patent.</p>

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<p>1 We disagree that FDA should -- how do I put this the right 2 way?</p> <p>3 We believe that the statute only allows -- allows for one 4 applicant to have a full 180-day exclusivity period. Whether a 5 later applicant can have an additional exclusivity period by 6 virtue of the nature of the filing that they're making -- if in 7 fact a patent-by-patent approach is imported into that part of 8 the analysis -- that that's sort of a step two to the analysis.</p> <p>9 I think that no matter what, the ANDA applicant who is the 10 first filer gets their 180-day exclusivity period. Then the 11 question becomes: Do you want to say that a later-in-time 12 applicant can get a 180-day exclusivity period of their own?</p> <p>13 But what the statute does not allow for is that the 14 180-day exclusivity period can be split simultaneously and shared 15 by multiple applicants. That is the point that Torpharm says is 16 nowhere found in the statute.</p> <p>17 THE COURT: I was just wondering: When you mention the 18 FDA's flip flops, is your current argument somewhat of a flip 19 flop for Torpharm? Hasn't Torpharm argued something differently 20 in another case?</p> <p>21 MS. MAZZOCHI: That might be the case if we'd actually 22 been prevailing on those cases, Your Honor.</p> <p>23 THE COURT: Go ahead. I didn't mean to prolong it on that 24 point.</p> <p>25 MS. MAZZOCHI: Oh, no, that's fine.</p>	<p>1 received the administrative record from FDA. 2 And as we raised in our reply briefs, FDA is basing its 3 decision to award a shared exclusivity to Alphapharm, based on 4 Alphapharm's alleged first filer status in connection with the 5 '449 patent. And that's the only patent that FDA is using to, if 6 you will, invite Alphapharm to share in the exclusivity table. 7 In our reply brief, we explain why the '449 patent is a 8 fairly unique patent here in view of the additional patents that 9 have been listed in the Orange Book, because the '449 patent -- 10 it's actually not a GSK patent.</p> <p>11 The '449 patent is a patent that relates to a method of 12 using Paroxetine -- I believe it's PMS -- to alleviate symptoms. 13 That patent was listed; Alphapharm managed to -- or FDA asserts 14 that Alphapharm certified to it. And FDA has taken the position 15 that there are -- there is an additional first filer who has 16 certified to that patent.</p> <p>17 FDA has also taken the position that Alphapharm's 18 activities with respect to the '449 patent can be used somehow to 19 block Torpharm's ability to enjoy its 180-day exclusivity period.</p> <p>20 We have two problems with this. First, under the existing 21 regulations, Torpharm did not have to certify to the '449 patent. 22 The reason why is because this patent was late-listed after 30 23 days, after our ANDA was already on file. So as a result, under 24 FDA's regulations, for the reasons I believe we explained in 25 greater detail in our reply brief, we did not have to certify to</p>
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<p>1 One thing that, with respect to FDA's flip flopping, FDA 2 has in fact indicated that the first filer approach is one that 3 is supported by the statute.</p> <p>4 To the extent FDA has engaged in these series of letter 5 rulings, the methodology that they are putting forth and the 6 results that they are obtaining, that in and of itself, prior to 7 their decision here, was never the subject of notice and comment 8 rule making. And we believe that it's because of that, because 9 there is no set standard, that we're starting to lead to the 10 arbitrary and capricious results that we're seeing here.</p> <p>11 Ultimately, Torpharm's position is that, under the first 12 filer approach, this Court should enjoin any other ANDA approval 13 that's going to encroach on Torpharm's unfettered exclusivity. 14 And, you know, the result is going to be the same, irrespective 15 of which approach, whether it's the cascading approach or the 16 first filer approach.</p> <p>17 Now the question becomes: What happens if you were to 18 accept FDA's approach? And for the reasons stated in our briefs, 19 we obviously do not believe that FDA's approach here is the 20 correct one.</p> <p>21 But we don't believe that even under FDA's current 22 rulings, that FDA is allowed to give multiple exclusivity rights 23 to multiple ANDA applicants, particularly Alphapharm here. The 24 reason why is because of the specific nature of the -- or the 25 identity of the patent, which we discovered after we finally</p>	<p>1 the '449 patent.</p> <p>2 Now, FDA's entire shared exclusivity regime arose out of 3 the concept that you are going to have ANDA applicants who are 4 going to be going head to head, mutually blocking one another, 5 such that no one would ever be able to get on the market absent 6 some type of shared exclusivity. And I believe they first 7 started this with the Cisplatin letter.</p> <p>8 The problem here is that Alphapharm is not blocking 9 Torpharm's ability to enter the market because, even if you 10 wanted to interpret the statute the way that FDA is suggesting 11 that it be read, by saying that Alphapharm, by being the first 12 filer on the '449 patent, is able to gain some type of 13 exclusivity rights, that can -- you can only have the 180-day 14 blocking scenario if Alphapharm is keeping Torpharm from entering 15 the market by virtue of the '449 patent. But since Torpharm 16 hasn't certified to the '449, there is no mutual blocking 17 scenario.</p> <p>18 Now, FDA is trying to take its ad hoc rulings one step 19 further and saying, well, Torpharm, because you are blocked by 20 Geneva on some other patents and Geneva is blocked by you on some 21 other patents, we're going to let Alphapharm take advantage of 22 the fact that Geneva -- and I believe they're referred to as 23 Company X in FDA's brief -- we're going to allow Alphapharm to 24 take advantage of Geneva's ability to block you in order to block 25 you; and now that you're blocked, you have to share with</p>

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<p style="text-align: right;">Page 14</p> <p>1 Alphapharm. 2 We believe that this type of interpretation is starting to 3 get so far afield and attenuated that this, too, amounts to 4 arbitrary and capricious agency action. Making matters worse, 5 the -- to the extent Alphapharm was, in fact, a first filer in 6 connection with the '449 patent, it was only on a narrow number 7 of dosages, not even the full number of approved doses. 8 It's not clear to us whether FDA is planning on giving 9 Alphapharm full approval for all of the dosage ranges, which 10 include 10, 20, 30, and 40 milligram doses, but here Alphapharm 11 only has a first filer status on the 10, 20, and 30 milligram 12 doses. The other company, Company Y, which we believe to be 13 Zenith Pharmaceuticals, was apparently first on this 40 milligram 14 tablet. 15 So now we have the situation where Apotex is going to be 16 required to share the entire Paroxetine market with Alphapharm 17 when Alphapharm didn't even make it to the patent office first on 18 all of the available doses; Alphapharm isn't even blocking 19 Torpharm directly. And the FDA says well, but that's still okay 20 because Alphapharm is blocking Geneva, Geneva is blocking you, so 21 we're going to let you all share. 22 Well, the problem that we have with that is -- and again, 23 this is based on -- this is information that we didn't find out 24 until FDA's submission of the surreply brief and Alphapharm's 25 submission of their surreply brief.</p>	<p style="text-align: right;">Page 16</p> <p>1 to get underneath the certification itself and challenge it. And 2 you know, they're going to say something about that. I imagine 3 there may be a response to that. 4 The fact is that this is their motion and it's their 5 burden; it's their burden to bring forth facts. They did not, in 6 their citizen petition, bring forth -- base their challenge on 7 this fact, just as they didn't in their initial papers. 8 Now, if they want to continue -- now, if the Court reaches 9 that fact, then, you know, perhaps there could be additional 10 litigation about it. But there's no basis for accepting this in 11 terms of a preliminary injunction motion. 12 Further, Your Honor, we put forth in the record the fact 13 there have been other first filers; we put forth the letters that 14 were sent. Now, they've been redacted because it's contrary to 15 FDA regulation to have the names put forth, but we've put forth 16 the letters to those other first filers, showing that they've 17 established first filer status on those other patents. 18 And really, what we're getting now is we're trying to get 19 more digging into the underlying facts and there is just no basis 20 for it at this 11th hour. 21 THE COURT: I'll reserve ruling on the motion for leave to 22 file, but you can continue. 23 I'm sorry. You're welcome to -- 24 MR. RAUBICHECK: Your Honor, on behalf of Alphapharm, I 25 would also like to oppose this --</p>
<p style="text-align: right;">Page 15</p> <p>1 The problem with all of this is that if Geneva is the 2 company who is being relied upon by FDA to try to block 3 Torpharm -- or, you know, by proxy, Alphapharm, via Geneva, is 4 used to block Torpharm -- based on the current administrative 5 record, Geneva didn't actually perfect their notice of a 6 paragraph IV certification for the '449 patent itself. 7 And we submitted to the Court today, and I believe we have 8 an additional copy for the Court if you would like it, explaining 9 this in a bit more detail. And we would ask that the Court 10 accept it because we do think that it helps to explain the 11 nuances of this, but -- 12 THE COURT: Well, on that point, let me just ask if there 13 is any objection to accepting this -- 14 MS. MAZZOCHI: I'm sure there will be. 15 THE COURT: -- filing today, the motion for leave to file 16 response to the surreply? 17 MR. STEARN: We would object, Your Honor. I got this 18 motion literally as I walked into court today. And further, Your 19 Honor, we really don't think -- this is just going to keep this 20 thing going because, you know, from our perspective, Your 21 Honor -- 22 THE COURT: Let me invite you up to the microphone. 23 MR. STEARN: Sure, Your Honor. 24 From our perspective, Your Honor, we put forth the fact of 25 which certifications were out there. This is a challenge to try</p>	<p style="text-align: right;">Page 17</p> <p>1 THE COURT: All right. 2 MR. RAUBICHECK: -- not only because it's an 11th hour 3 filing with which we were just served literally as we came in, 4 but also because what it is going to invite is it's going to 5 invite bringing a whole new party into this case and digging with 6 respect to facts that aren't even in the administrative record of 7 this case, because this issue wasn't raised by any party until 8 this afternoon. 9 FDA would be required to go back, if Your Honor wanted 10 more delving into this, find out what the administrative record 11 contains with respect to a whole separate ANDA, which is 12 Geneva's, and they're not even a party to this action. 13 It seems to me we ought to focus on the facts here. 14 That's Alphapharm's position. 15 THE COURT: Thank you. 16 MS. MAZZOCHI: And, Your Honor, if I may respond. 17 Part of the reason why we've been somewhat hampered in 18 this is because FDA does in fact keep all of the notice letters 19 confidential. They did not identify the companies who were 20 involved in this and we've been getting the record in dribs and 21 drabs. And as soon as we identified this as -- as soon as we 22 were able to identify that Geneva was in fact the company that 23 was at issue with respect to the '449 patent, which we only found 24 out in FDA's surreply brief, we immediately brought this to the 25 attention of the Court.</p>

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<p style="text-align: right;">Page 18</p> <p>1 And if I may, I'd like to explain in a bit more detail, 2 first, as to why the present administrative record, as it 3 currently stands, does in fact indicate that the '449 patent 4 certification by Geneva is, in fact, not a paragraph IV 5 certification that is proper. And I think that's critical 6 because --</p> <p>7 THE COURT: Well, forgive me for interrupting. Do you 8 want to do that in support of this current motion for leave to 9 file or do you want to do that in support of the previous motions 10 filed?</p> <p>11 MS. MAZZOCHI: Personally, Your Honor, I think that they 12 both are essentially one and the same because --</p> <p>13 THE COURT: Because I'm going to reserve ruling on this 14 motion filed today.</p> <p>15 MS. MAZZOCHI: Right.</p> <p>16 THE COURT: So --</p> <p>17 MS. MAZZOCHI: That I understand.</p> <p>18 THE COURT: So your clock is still running. But go ahead.</p> <p>19 MS. MAZZOCHI: That's fine.</p> <p>20 The whole basis -- the whole rationale by FDA as to why 21 they think they're entitled to award Alphapharm with final 22 approval potentially tomorrow is because they said that 23 Alphapharm is, in fact, one of the four companies that's allowed 24 to engage in shared exclusivity status.</p> <p>25 However, if in fact Alphapharm is not a first filer who</p>	<p style="text-align: right;">Page 20</p> <p>1 The reason why can be found both at administrative record 2 tab 23 as well as in Alphapharm's surreply; I believe it's 3 Mr. Raubicheck's Exhibit A, attached to his declaration. 4 Exhibit A attached to his declaration indicates that 5 Geneva believed that GSK was the owner of the '449 patent. 6 That's not the case. The '449 patent is not owned by Glaxo and, 7 under the statute, in order for notice of a paragraph IV 8 certification to be effective -- and this is found at 21 U.S.C. 9 355(j)(2)(B)(i)(I) -- the applicant is required to give "each 10 owner of the patent which is the subject of the certification or 11 the representative of such owner designated to receive such 12 notice" proof that they have submitted -- or notice that they 13 have submitted a paragraph IV certification.</p> <p>14 And the reason why this is important is because if, in 15 particular, validity issues are going to be involved in any 16 patent challenge, you want to -- and someone is, you know, going 17 to, in theory, obtain a benefit by sticking their neck out to go 18 litigate, you want to make sure that the patent owner has been 19 provided with notice so that they can potentially come into the 20 fold.</p> <p>21 Here, according to the notice letter that is attached to 22 Mr. Raubicheck's declaration, Geneva only sent their paragraph IV 23 notice to SmithKline. Tab 23 of the administrative record is a 24 submission of the '449 patent to FDA. In that submission, it is 25 the named inventor of the '449 patent, and I believe his name is</p>
<p style="text-align: right;">Page 19</p> <p>1 has blocked somebody else -- i.e., Geneva -- then Alphapharm 2 should not be awarded any shared exclusivity at all.</p> <p>3 And if I may, Your Honor, I've prepared a couple of 4 demonstrative exhibits just to explain why this is in fact the 5 case. And if I may, I'd like to provide the Court with a copy.</p> <p>6 The first illustration that I've provided you sort of goes 7 through what FDA considers to be its mutual blocking scenario. 8 And in particular, I would like to focus on the '449 patent.</p> <p>9 Now, when FDA applies its shared exclusivity regime, what 10 FDA does is it says: Who are all of the first filers? The next 11 question that it asks is: Are these first filers blocking any 12 other first filers? If they are, then FDA invites them into the 13 fold and says, you know, we'll determine whether or not you can 14 all share.</p> <p>15 Here the only patent that Alphapharm has any first filer 16 status for is the '449 patent. And FDA has taken the position 17 that the 10, 20, and 30 milligram certification by Alphapharm is 18 blocking Geneva; i.e., Company X. With respect to the 40 19 milligram dosage, Zenith is blocking Alphapharm.</p> <p>20 If we go to the next page, then we get to what we consider 21 to be the blocking scenario, based on what facts are available in 22 the administrative record. We believe that the administrative 23 record does not support a showing that Geneva did, in fact, 24 submit an appropriate paragraph IV certification with respect to 25 the '449 patent.</p>	<p style="text-align: right;">Page 21</p> <p>1 Dr. Norden, and his agent is also -- his agent or representative 2 is also identified, and I believe his name is Jeffrey Oster. 3 Neither of these people are affiliated or associated with 4 GlaxoSmithKline.</p> <p>5 So the fact that Geneva may have sent some notice to 6 SmithKline is not capable of creating a true paragraph IV 7 certification that is proper and perfected under the statute.</p> <p>8 And the significance of this, of course, is clear because 9 if -- well, hopefully I can make it clear -- because if Geneva 10 has not, in fact, certified for the '449 patent, Alphapharm 11 cannot block Geneva.</p> <p>12 And Geneva was not even required to submit a paragraph IV 13 certification for the '449 patent for the same reason that 14 Torpharm was not required to submit a paragraph IV certification; 15 namely, because that patent was late-listed.</p> <p>16 So Geneva wasn't required to submit a paragraph IV 17 certification for the '449 patent. To the extent they may have 18 attempted it, it may not even be effective. Based on the 19 administrative record, it appears to be wholly defective.</p> <p>20 So if Geneva is out of the picture, then we get to the 21 blocking scenario that's present on the record, as we graphically 22 depict it here, which is that there is no first filer on the '449 23 patent who is blocking anyone on the 10, 20, 30 milligram dosage 24 forms.</p> <p>25 To the extent that Zenith has prepared a 40 milligram</p>

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<p style="text-align: right;">Page 22</p> <p>1 first -- or has obtained a 40 milligram first filer status, the 2 only person that they could be blocking would be Alphapharm, but 3 Alphapharm is no longer part of the equation because Alphapharm 4 doesn't have the true first filer status. 5 So what that ultimately means is that Alphapharm really 6 does not have a seat at the table. Alphapharm should not have 7 been entitled to any shared exclusivity in the first instance. 8 And in terms of, you know, which party is in the best 9 position to determine this, in theory, this should have been FDA. 10 As to whether FDA actually did go back to -- or when it 11 even awarded its shared exclusivity, whether FDA actually 12 confirmed that Geneva did in fact submit a true and proper 13 paragraph IV certification for the '449 patent, it appears that 14 the agency did not, in fact, consider it. Or if there was a 15 proper certification, evidence of that is not provided here in 16 the administrative record. 17 And if I can just direct your attention to the next 18 illustration that we provided you with, the only reason why FDA 19 says that Alphapharm is entitled to shared exclusivity, despite 20 the fact Alphapharm cannot block Torpharm, is because Alphapharm 21 on the '449 patent was blocking Geneva, who in turn was blocking 22 Torpharm. 23 If you take that arrow of the '449 patent out of the 24 equation, Alphapharm does not mutually block anybody. And the 25 entire purpose of the shared exclusivity regime, according to</p>	<p style="text-align: right;">Page 24</p> <p>1 but even if it is to be followed, on the facts here, Alphapharm 2 still is not entitled to any shared exclusivity and final 3 approval of its ANDA should be postponed until on or about 4 March 6th, 2004. 5 Thank you. 6 THE COURT: All right. Thank you. 7 Mr. Stearn, do you want to go first? 8 MR. STEARN: Yes, Your Honor. Thank you, Your Honor. 9 Your Honor, the facts on this record right now are that 10 Torpharm filed first paragraph IV certifications with regard to 11 certain patents and that others filed -- including Alphapharm -- 12 filed paragraph IV certifications as to other patents. 13 In our surreply brief, we put forward who were the first 14 filers. It's not part of the administrative record because the 15 applications by law of other applicants are not disclosed and 16 it's not -- and furthermore, in the citizen petition process, 17 this is not something that -- anything that was raised by 18 Torpharm. 19 In fact, a lot of these arguments I'm hearing for the 20 first time today. And it's entirely a new argument to say 21 that -- to start challenging the paragraph IV certifications. 22 With regard to the law, the statute and the regulations, 23 Your Honor, the statute, which we keep hearing is obvious, is not 24 really made much reference to by Torpharm. What the statute 25 actually says -- it actually regards when FDA approves.</p>
<p style="text-align: right;">Page 23</p> <p>1 FDA, was to ensure that people who were mutually blocking each 2 other, by sharing exclusivities, would no longer be mutually 3 blocking each other. Here, if Alphapharm is not mutually 4 blocking any of the other first filers, there's no reason for 5 Alphapharm to share in any 180-day exclusivity period. 6 So -- I believe I'm getting close in my time, so if I may 7 conclude, even if we wanted to accept the most far out 8 permutation of FDA's view as to why shared exclusivity directly 9 or indirectly applies to devalue Torpharm's 180-day exclusivity 10 period here, the facts are simply not present on this record to 11 permit final approval of Alphapharm's ANDA and certainly not for 12 all of the approved doses. 13 And, Your Honor, I know that several of these arguments do 14 involve some new permutations of the facts and for that I do 15 apologize. Again, we are somewhat hampered by our own ability to 16 gain access to the full administrative record before the FDA. 17 But ultimately, we believe that the law -- the first 18 applicant approach is the proper one. To the extent there is to 19 be any sort of equitable considerations or a patent-by-patent 20 approach with respect to later-listed patents, we believe that 21 the cascading approach is the only one that remains true to the 22 spirit of Hatch-Waxman by actually providing the required 23 incentive to go out and litigate and challenge later patents. 24 And with respect to the shared exclusivity regime that FDA 25 has proposed, we believe that it is not supported by the statute,</p>	<p style="text-align: right;">Page 25</p> <p>1 It does not grant this exclusivity right, which is 2 indivisible; rather, where there is a certification and there's a 3 previous certification regarding that patent, blocking applies. 4 Over and over again, the statute refers to these 5 certifications as patent-specific. Specifically, the 6 certifications are "to each patent" under 355(j)(2)(A)(vii). The 7 certifications must state that, quote, "such patent," unquote, is 8 not infringed. Further, the exclusivity trigger is by a decision 9 on, quote, "the patent which is the subject of the 10 certification." 11 All right. So by the actual words of the statute, the 12 actual word of the statute require a patent-by-a-patent approach. 13 Further, the regulation, which is even more direct, states 14 that where the application has a certification and there's a 15 previously submitted application containing a certification, 16 quote, "to the same patent," blocking applies. 17 Furthermore, the regulations actually define who is the 18 first applicant by saying, quote, "the applicant submitting the 19 first application," unquote, is the one that submits an 20 application and where that application contains a certification 21 to the specific patent at issue. 22 THE COURT: Well, that assumes that the regulation 23 accurately and properly or permissibly interprets the statute, so 24 go back to the statute. 25 MR. STEARN: I would be happy to go back to the statute,</p>

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<p style="text-align: right;">Page 26</p> <p>1 Your Honor.</p> <p>2 And in that statute, if I may, the statute states "if the</p> <p>3 application contains a certification described in subclause (IV)</p> <p>4 of paragraph (2)(A)(vii)" — and that's the case here for</p> <p>5 Torpharm's application as well as the other applicants, and it's</p> <p>6 for a drug —</p> <p>7 THE COURT: The application referred to in the language</p> <p>8 you had started to read from does not refer to Torpharm's</p> <p>9 application; it refers to subsequent applications.</p> <p>10 MR. STEARN: Right. Well, Your Honor, when it says the —</p> <p>11 it says — it must be for a drug for which a previous application</p> <p>12 has been submitted —</p> <p>13 THE COURT: That's Torpharm.</p> <p>14 MR. STEARN: — under this subsection containing such a</p> <p>15 certification.</p> <p>16 Torpharm's application contained such a certification at</p> <p>17 the time that they amended these paragraph IV certifications.</p> <p>18 THE COURT: Well, where does the statute say at the time</p> <p>19 it amended the paragraph IV certifications?</p> <p>20 MR. STEARN: Well, what the statute says is — the statute</p> <p>21 says where there is an application containing such a</p> <p>22 certification, the application contain such a certification at</p> <p>23 the time that the certification is filed.</p> <p>24 THE COURT: Right.</p> <p>25 MR. STEARN: Is that clear? I just want to make sure I'm</p>	<p style="text-align: right;">Page 28</p> <p>1 late-listed patents?</p> <p>2 MR. STEARN: Well, Your Honor, when — it does so</p> <p>3 because — first of all, it requires — it requires an</p> <p>4 approach — every time that there's a certification, it requires</p> <p>5 the FDA to look at it because, as I said, it's patent-specific.</p> <p>6 So every certification must be looked at anew. And when</p> <p>7 there's an amendment — that is, when there's a new paragraph IV</p> <p>8 certification that's made — until they make that paragraph IV</p> <p>9 certification, Torpharm's application is not an application</p> <p>10 containing that certification.</p> <p>11 Is that — am I making myself clear?</p> <p>12 THE COURT: I can't say I followed that one.</p> <p>13 MR. STEARN: Okay. Your Honor, the point of all those —</p> <p>14 that language that I've gone through over — about all the</p> <p>15 "patent-specific" is this: It attaches to the patent itself.</p> <p>16 That is, the Court must consider each patent as it comes and each</p> <p>17 patent and whether or not there's been a previous certification</p> <p>18 to that patent.</p> <p>19 And, Your Honor, to the extent that this is unclear and to</p> <p>20 the extent that it's ambiguous, the agency's interpretation must</p> <p>21 govern.</p> <p>22 Now, Torpharm admits —</p> <p>23 THE COURT: Okay. But before you get there, show me where</p> <p>24 the statutory language makes clear some discussion about having</p> <p>25 to look at patent certifications that are made for later-filed</p>
<p style="text-align: right;">Page 27</p> <p>1 making myself clear.</p> <p>2 THE COURT: Well, that sounds like a different time</p> <p>3 reference from what you said a moment ago. I thought you were</p> <p>4 referring to a time in which Torpharm had filed amended paragraph</p> <p>5 IVs after Glexo had submitted these eight or nine additional</p> <p>6 patents.</p> <p>7 MR. STEARN: Well, yes, Your Honor. With regard to those</p> <p>8 patent certifications, FDA's interpretation as well as the</p> <p>9 wording of the statute says that the statute is — is that if the</p> <p>10 application contains a certification, okay — which it does here;</p> <p>11 it's a certification; and it does for Torpharm — and it's for a</p> <p>12 drug for which a previous application has been submitted</p> <p>13 containing such a certification.</p> <p>14 So the other applications — for instance, Company X's, as</p> <p>15 we call it — was a previous application containing that</p> <p>16 certification, because Torpharm's application only became such an</p> <p>17 application at the time that they amended this — these —</p> <p>18 THE COURT: "They" who?</p> <p>19 MR. STEARN: Torpharm's application only became an</p> <p>20 application containing such a certification — that is, these</p> <p>21 late-listed patents — at the time that they amended their</p> <p>22 paragraph IV certification.</p> <p>23 THE COURT: Well, that's true, but where does this</p> <p>24 language of the statute narrow us to a time at which Torpharm has</p> <p>25 filed an amended ANDA to include certifications concerning the</p>	<p style="text-align: right;">Page 29</p> <p>1 patents.</p> <p>2 MR. STEARN: Okay. Well, Your Honor, I'd take exactly</p> <p>3 what it says in the statute itself. First, it says "if the</p> <p>4 application contains a certification." There's no time</p> <p>5 limitation on that. There's no — it doesn't say "once this" —</p> <p>6 you know, the first certification. "When it contains a</p> <p>7 certification, describe."</p> <p>8 And the "describe" — and what the reference is is to each</p> <p>9 patent. So — thus it requires the FDA to look at those amended</p> <p>10 certifications first, in the first instance, to determine whether</p> <p>11 there's —</p> <p>12 THE COURT: You keep saying "amended certifications."</p> <p>13 MR. STEARN: Well, I should say — I shouldn't say</p> <p>14 "amended certifications," Your Honor. I should say "a new</p> <p>15 certification — a new paragraph IV certification," which is a</p> <p>16 change in their application.</p> <p>17 THE COURT: Well, the statute, at the point from which you</p> <p>18 are beginning to read from it, says: "If the application</p> <p>19 contains a certification and is for a drug" — and it goes on.</p> <p>20 MR. STEARN: Right.</p> <p>21 THE COURT: That application has to do with any ANDAs that</p> <p>22 come after someone else has filed an ANDA, correct?</p> <p>23 MR. STEARN: Well, Your Honor, it says — I'm not sure I</p> <p>24 follow your question. Let me make sure I understand your</p> <p>25 question.</p>

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<p style="text-align: right;">Page 30</p> <p>1 THE COURT: To complete the language, it says: "If the 2 application — if the application contains a certification and is 3 for a drug for which a previous application has been submitted 4 under this section containing such a certification" —</p> <p>5 MR. STEARN: Right.</p> <p>6 THE COURT: Now, that clause contains two different 7 references to the word "application."</p> <p>8 MR. STEARN: Right.</p> <p>9 THE COURT: The first reference — the second reference to 10 the word application is modified by "previous."</p> <p>11 MR. STEARN: Right.</p> <p>12 THE COURT: The second reference to application — namely, 13 "previous application" — must necessarily refer to one that had 14 been filed earlier than the application referred to in the 15 beginning of that quote, correct?</p> <p>16 MR. STEARN: Well, Your Honor, first, I'd say that 17 "application" is also modified by the clause "containing such a 18 certification."</p> <p>19 THE COURT: Assume that the previous application has a 20 certification under paragraph IV for a patent.</p> <p>21 MR. STEARN: Right.</p> <p>22 THE COURT: The beginning of that clause, then, would be: 23 "If the application," meaning a subsequent application, "contains 24 a certification under paragraph IV for the patent."</p> <p>25 MR. STEARN: Right. That's correct.</p>	<p style="text-align: right;">Page 32</p> <p>1 MR. STEARN: Correct.</p> <p>2 THE COURT: We won't name them, but other companies — 3 Alphapharm and some other companies — file ANDAs for Paroxetine 4 afterwards.</p> <p>5 MR. STEARN: Yes.</p> <p>6 THE COURT: Right?</p> <p>7 MR. STEARN: Correct.</p> <p>8 THE COURT: Do those ANDAs that the other companies filed 9 contain paragraph IV certifications about the '723 patent?</p> <p>10 MR. STEARN: Yes.</p> <p>11 THE COURT: All right. Of what significance is that?</p> <p>12 MR. STEARN: Well, the significance of that first part 13 under our approach, Your Honor, is that for — is that other 14 applicants can be blocked — or I should say the agency blocks 15 the applications — approval of these other applications that 16 have been filed, okay.</p> <p>17 But what this case — and I don't think anybody is saying 18 anything different about the '723 patent.</p> <p>19 What this case is about at this point, Your Honor, I think 20 is these other patents. And with these other patents — that is, 21 Company X files an application; that's an application; and with 22 regard to that, the application of the statute — the 23 certifications are patent-specific — those applications — 24 there's previously filed applications containing the 25 certification before Torpharm. That is, with regard to the other</p>
<p style="text-align: right;">Page 31</p> <p>1 THE COURT: Okay.</p> <p>2 MR. STEARN: And, Your Honor, we submit that that is the 3 case with Torpharm's — with certain of Torpharm's 4 certifications.</p> <p>5 THE COURT: Well, take the very first ANDA that it filed.</p> <p>6 MR. STEARN: Yes.</p> <p>7 THE COURT: It had a certification in that first — in the 8 ANDA that it filed —</p> <p>9 MR. STEARN: Yes.</p> <p>10 THE COURT: — back in March of '98 —</p> <p>11 MR. STEARN: Yes.</p> <p>12 THE COURT: — for the '723 patent.</p> <p>13 MR. STEARN: Yes. And by doing so, they had blocking 14 rights — or I should say there was a block of other applicants; 15 but similarly, other applicants that filed the first paragraph IV 16 certifications to other patents had the ability — and that's 17 what we call Company X and Company Y — FDA was required to block 18 Torpharm's application as well.</p> <p>19 THE COURT: Well, let's try to find where in the statute 20 that result is required. And let's look at it in terms of the 21 facts. —</p> <p>22 Torpharm files its ANDA with a paragraph IV 23 certification —</p> <p>24 MR. STEARN: Yes.</p> <p>25 THE COURT: — for patent '723.</p>	<p style="text-align: right;">Page 33</p> <p>1 patents that are at issue here, the '132 patent and so on. 2 In other words, there are previous applications containing 3 that certification that have been filed.</p> <p>4 Is that clear? At least our point, is that point clear?</p> <p>5 THE COURT: Go ahead.</p> <p>6 MR. STEARN: Your Honor, further, let me go on to the next 7 point, which is that, to the extent it's ambiguous, the extent — 8 whether or not this filing is an ambiguous term, then the Court 9 must defer to FDA's interpretation and its regulation and —</p> <p>10 THE COURT: What if it's not?</p> <p>11 MR. STEARN: Well, Your Honor, if it's not ambiguous, the 12 question is — the Court must apply it?</p> <p>13 There's some restrictions in terms of the applications 14 straightforwardly. For instance, if it produces an absurd 15 result, which — or, it's out — the Court must consider other 16 provisions of the statute in terms of whether or not those — 17 that makes sense in terms of the statute.</p> <p>18 But yes, that's the first step, to look at the statute.</p> <p>19 We submit, Your Honor, that the interpretation that most closely 20 follows is the one that is patent-specific that covers the 21 patents.</p> <p>22 THE COURT: Torpharm has argued that the language is 23 unambiguous and that it requires a first filer drug-specific 24 approach. What is the result — what is the absurd result that 25 flows from that argument?</p>

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<p style="text-align: right;">Page 34</p> <p>1 MR. STEARN: Well, Your Honor, I don't -- that's not -- I 2 wouldn't -- I would say that the problem that we have -- we have 3 multiple problems with that, but first is that by doing so, we 4 would say that it's not an unambiguous -- that's not an 5 unambiguous reading of the statute; in other words, that the 6 statute does not call for that because the statute repeatedly 7 refers to certifications as being specific. It says there's -- 8 it requires, wherever there is "a certification." 9 And just as this Court applied "a court," whether it's a 10 District Court or an appellate court, "a certification" applies 11 wherever there is a certification. So we don't think that that 12 closely follows the statutory language. 13 We also would submit that it doesn't follow the overall 14 structure of Hatch-Waxman. And we put forward arguments about 15 that in our briefs, Your Honor, in that it does deprive 16 incentives of other applicants to file and challenge those 17 late-listed patents, in the sense that by limiting it to one 18 first applicant, it takes away an incentive to challenge those 19 late-listed patents, which we think is inconsistent with 20 Hatch-Waxman. 21 I would add with regard to the ambiguity of the statute, 22 Your Honor, this District Court, in Dr. Reddy's opinion, page 27, 23 did call this provision ambiguous. If I could quote from page 24 27, it says: "But considering section 355(j) as a whole, the 25 phrase, quote, 'a drug for which a previous application has been</p>	<p style="text-align: right;">Page 36</p> <p>1 point this Court must address this question because we believe 2 that at some point, step 2 Chevron comes into account. 3 But FDA issued a regulation on this point. On this issue, 4 the regulation is patent specific, and further, it says FDA's 5 interpretation of its own regulation is entitled to substantial 6 deference under Auer and Bristol-Myers. Torpharm has never 7 responded to that argument. 8 Furthermore, case law, such as American Express versus 9 United States -- 10 THE COURT REPORTER: I'm sorry. Please slow down. 11 MR. STEARN: Further, there's case law, including American 12 Express versus the United States, 262 F.3d 1376; the Barnhart 13 case, which is cited in our brief, makes clear that this 14 continues despite Christensen. 15 Secondly, Mead, contrary to what Torpharm has cited, does 16 not stand for the proposition that there must be rule making, in 17 fact, to take out deference. It says: "Delegation of such 18 authority may be shown in a variety of ways, such as by an 19 agency's power to engage in adjudication," et cetera. 20 And FDA makes approval decisions in this case. The 21 standard -- there's a standard under Federal Election Commission 22 versus NRA, 254 F.3d 173, which is applicable in this circuit, 23 which says: "Where its actions are taken pursuant to a detailed 24 statutory procedure, fulfilling its statutory responsibilities 25 has the force of law. The agency is entitled to deference."</p>
<p style="text-align: right;">Page 35</p> <p>1 submitted containing such certification,' unquote, is ambiguous." 2 That's the precedent I would submit to this Court. 3 Further -- 4 THE COURT: Is it binding? 5 MR. STEARN: -- Your Honor, on page 28 -- 6 THE COURT: Is it binding? 7 MR. STEARN: I think it's one of the exhibits to our -- 8 THE COURT: Is that precedent binding on me? 9 MR. STEARN: Well, Your Honor, I believe that it is in the 10 sense that this is a question -- I mean, in terms of considering 11 whether or not there's a -- the issue in that case was whether 12 the ANDA contained a paragraph IV certification on a patent at 13 the time of FDA's exclusivity decision. So it was in terms of 14 the timing of the exclusivity decision. So it was trying to 15 determine this issue about -- that Your Honor is asking me about. 16 And further, on page 28 of that same decision, it says 17 quote "when certifications are added post-submission, comma, the 18 ANDA was not, quote, 'submitted containing,' unquote, them." 19 So in other words, the -- Dr. Reddy's decision on page 28 20 talks about the filing time of these certifications as -- filing 21 times with regard to the exclusivity determination as being the 22 time of the filing of the paragraph IV certifications. 23 Very briefly, Your Honor -- I think I'm about out of 24 time -- but I would just add, very briefly, with regard to 25 deference, first, FDA did, in fact -- and we believe that at some</p>	<p style="text-align: right;">Page 37</p> <p>1 And finally, we believe the agency is entitled to Skidmore 2 deference. 3 With that, Your Honor, I think my time is up, but I'm 4 happy to respond to any questions the Court has. 5 THE COURT: All right. Thank you. 6 Mr. Raubicheck. 7 MR. RAUBICHECK: Thank you, Your Honor. 8 I'm going to try to focus on as many new points and not 9 repeat what other counsel have said, with the sole exception of 10 first addressing Your Honor's concern about the statutory 11 language. 12 If you focus on the statute that Your Honor was looking 13 at, 21 U.S.C. section 355(j)(5)(B)(iv), that is the 180-day 14 exclusivity provision in the statute. As Your Honor was pointing 15 out, the statute says: "If the application contains a 16 certification described in" -- and they refer to the 17 certification section of the statute -- "and is for a drug for 18 which a previous application has been submitted under this 19 section containing such a certification." 20 Just looking at those words, in Your Honor's example, 21 Torpharm, as the first ANDA applicant for Paroxetine, filed its 22 ANDA with a paragraph IV certification on the '723 patent. At 23 that point in time, Torpharm was first to file with respect to 24 the '723 patent. 25 THE COURT: And with respect to Paroxetine tablets.</p>

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<p style="text-align: right;">Page 38</p> <p>1 MR. RAUBICHECK: And with respect to Paroxetine tablets. 2 THE COURT: Generic Paroxetine. 3 MR. RAUBICHECK: Generic Paroxetine. Correct. Correct. 4 But fortunately or unfortunately, this world of 5 certifications against listed Orange Book patents isn't static. 6 That particular event, the first filer's certification against 7 the first listed Orange Book patent — 8 THE COURT: The only listed Orange Book patent. 9 MR. RAUBICHECK: At the time. At the time. 10 THE COURT: Yeah. 11 MR. RAUBICHECK: Unfortunately, that situation is not 12 static. It changes over the course of time. In this particular 13 situation, SmithKline Beecham was able, subsequent to the listing 14 of the '732 patent, to obtain eight additional patents from the 15 U.S. Patent and Trademark office over a two-year span. And what 16 FDA — what the statute requires — now let's flip back to the 17 reference. 18 And "if the application contains a certification described 19 in subparagraph (IV) of paragraph (j)(2)(A)(vi)" — let's turn to 20 21 U.S.C. section 355(j)(2)(A)(vi); it says that "each ANDA must 21 contain a certification, in the opinion of the applicant and to 22 the best of his knowledge, with respect to each patent which 23 claims the listed drug or claims the use for which the applicant 24 is seeking approval, that such patent is invalid or will not be 25 infringed."</p>	<p style="text-align: right;">Page 40</p> <p>1 I have to go back and amend your ANDA to certify against any newly 2 issued patent coming out of the PTO that is given to the FDA by 3 the brand that goes in the Orange Book. 4 THE COURT: But where in the statute does it say that 5 that, therefore, eliminates the first filer's status as a first 6 filer? 7 MR. RAUBICHECK: I'll tell you where it says that. If you 8 go back to the exclusivity language that we were talking about in 9 section 355(j)(5)(B)(iv): "If the application contains a 10 certification described in paragraph IV and is for a drug for 11 which a previous application has been submitted under this 12 section containing such a certification." 13 When Torpharm filed, they were the previous application 14 containing such a certification with respect to the patent that 15 was listed at the time, which was the '723 patent. Later on, 16 however, as the '449 patent and these other patents started 17 getting listed in the Orange Book, and as other applicants came 18 to file, it came to pass that Torpharm wasn't as quick on the 19 trigger as they could have been. In other words, they didn't 20 amend when those new patents got into the Orange Book right away. 21 For some inexplicable reason, they waited and these other 22 applicants got in there with their paragraph IV certifications 23 against these newly listed patents. 24 So that — let's just take the — another — patent X, for 25 example.</p>
<p style="text-align: right;">Page 39</p> <p>1 THE COURT: And which patents claimed the Paroxetine drug 2 when Torpharm filed its answer? 3 MR. RAUBICHECK: Just the '723. But thereafter — and 4 this has happened frequently over the course of Hatch-Waxman's 5 history — brand name companies, in order to prolong their 6 monopolies, keep getting new patents. That's part of the game. 7 They've wanted more 30-month stays. Congress just recently 8 stepped in to stop that and said you only get — now you only get 9 one 30-month stay. 10 But we're operating here under the former rules because 11 that's not retroactive. 12 SmithKline went ahead and got eight additional patents. 13 And the world wasn't static then either because you had 14 subsequent ANDA applicants like Alphapharm, like Geneva, like 15 Zenith that come along. And as they file their ANDAs, they had 16 to certify against whatever patents were in the Orange Book as of 17 the time they filed their subsequent paragraph IV applications. 18 THE COURT: Although isn't, really, Hatch-Waxman intended 19 to try to get these generic manufacturers to move as quickly as 20 they can to file? 21 MR. RAUBICHECK: Absolutely. But the statute slows them 22 down by "each patent" language. The statute basically says, 23 okay, if the patent owner gets another patent later on and your 24 application is still pending at FDA, because it usually takes 25 about two years to get ANDA approval, then the statute says you</p>	<p style="text-align: right;">Page 41</p> <p>1 THE COURT: But those companies, when they filed their 2 ANDAs, for them to be complete ANDA's worthy of consideration -- 3 MR. RAUBICHECK: Right. 4 THE COURT: -- they had to contain paragraph IV 5 certifications about the '723 patent. 6 MR. RAUBICHECK: Correct. But also against all the 7 others. 8 THE COURT: And that eliminates the fact that Torpharm had 9 filed before everybody else on the '723 patent? 10 MR. RAUBICHECK: No, it didn't eliminate that fact. 11 That's the whole purpose -- that's the whole hangup FDA has had 12 with these mutually blocking exclusivities. 13 Because let's take patent — let's take a hypothetical 14 patent '123. My client Alphapharm comes along and, 15 hypothetically, let's say, we're the second filer. We file our 16 ANDA after Torpharm. We're second on the '723 patent, but when 17 we file our ANDA, we see that there's the '123 patent in there as 18 well as the '723, so we have to certify against both. 19 Torpharm could have certified against the '123 because it 20 was in the Orange Book for a while, but for some reason, they 21 didn't. They didn't amend, as the statute requires them to 22 certify against each patent. And so on the '123 patent -- 23 THE COURT: Well, they didn't do it then. 24 MR. RAUBICHECK: -- Alphapharm became -- 25 I'm sorry, Your Honor.</p>

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<p style="text-align: right;">Page 42</p> <p>1 THE COURT: They didn't do it then. 2 MR. RAUBICHECK: Correct. Or before then. Or before 3 then. 4 Under my example, Alphapharm's '123 application becomes 5 the previous application with a certification on the '123 patent. 6 And when Torpharm gets around to amending and filing, then 7 Torpharm is the subsequent application as to that patent. That's 8 the way the system works. That's the way FDA has been 9 interpreting it for ten years.</p> <p>10 This patent-by-patent exclusivity regulation which spells 11 this out was part of the final ANDA regulations promulgated in 12 1994 and industry and FDA have been operating under this for some 13 time.</p> <p>14 THE COURT: Well, you're right. Did —</p> <p>15 MR. RAUBICHECK: And nobody until this case — because 16 let's be clear what Torpharm really wants here. They're 17 basically saying, we're making 265 million dollars off our 18 180-day exclusivity, according to their own papers. We want it 19 all. We think we should have it all, even though we weren't 20 first to file on at least four or five subsequently listed 21 patents in the Orange Book. And these other guys should get 22 nothing.</p> <p>23 And what they're really fighting for is to be the sole 24 generic applicant into the marketplace for the full 180 days. 25 But according to the record, since September 8th, when they went</p>	<p style="text-align: right;">Page 44</p> <p>1 litigating against the same Torpharm. 2 THE COURT: What case did you cite? 3 MR. RAUBICHECK: It involves the drug gabapentin and the 4 name of the case is Purepac and Torpharm versus — Purepac and 5 Torpharm versus FDA. They're consolidated actions. 6 In that case, Torpharm is taking the position we want a 7 share of exclusivity. That case was argued — I argued that case 8 in this very building at the end of November and we're waiting 9 for a decision. It doesn't involve the validity of the shared 10 exclusivity principle, but that's what they're after in that case 11 because in that case, they say we're first to file on one patent; 12 these other guys are first to file on another. We should get a 13 share of the exclusivity.</p> <p>14 Now they're here before this Court and saying we should 15 get it all because of this interpretation of the statute that 16 seeks to supplant what FDA has already decided. If you go to the 17 July 30th decision, where FDA takes eight to nine pages to spell 18 out for each of the applicants what the shared exclusivity 19 principle is in the mutually blocking context, which it did in 20 the Omeprazol situation a couple years ago, which it did in the 21 Cisplatin situation back in 1999, basically, FDA said the way the 22 statute reads, we have two choices: We can either do the 23 one-first-applicant approach that Torpharm advocates or we could 24 adopt a shared exclusivity approach, whereby we will award each 25 first filer when there are multiple patents that are listed and</p>
<p style="text-align: right;">Page 43</p> <p>1 on the market, they've made 170 million dollars off this drug in 2 sales. 3 But — so what they're trying to do is not only get that 4 extra 50 million bucks, but they're trying to take down with them 5 the whole patent-by-patent exclusivity regulation and scheme that 6 FDA set up ten years ago and they're trying to vitiate the whole 7 shared exclusivity principle that FDA derived from that scheme 8 when you have situations — and this is the fourth one that's 9 occurred in the last three or so years — they're trying to tear 10 that whole thing down just so they can get the extra 50 million 11 bucks.</p> <p>12 And we — you know, basically, it's our position, as is 13 the FDA's, that the patent-by-patent scheme is inherent in the 14 statutory language of "each patent" — and the patent in the two 15 sections we've been talking about.</p> <p>16 And if the first filer isn't the first to file on all, as 17 a matter of point in time, then that first filer becomes a 18 subsequent filer on subsequently issued patents on which it slept 19 on its opportunity, because these — the brand company puts these 20 into FDA; they go into the Orange Book as soon as they come out 21 of the PTO.</p> <p>22 If Torpharm had wanted to be first, they knew what FDA's 23 interpretation was. As a matter of fact, and I'll point this out 24 because Your Honor mentioned it in the gabapentin litigation 25 that's in the D.C. circuit, in which one of my clients is</p>	<p style="text-align: right;">Page 45</p> <p>1 different first filers. 2 And FDA made the choice that it would be more consistent 3 with the language of these statutes that are before you to adopt 4 a shared exclusivity approach. And as I'm sure Your Honor is 5 well aware, the Federal Courts will not disturb a rational choice 6 of an administrative agency if that choice is made under a 7 permissible construction of the statute. 8 You know, it's like going back to the old — one of the 9 early FDA cases, actually, that was ever decided back in 1943 by 10 the U.S. Supreme Court. The industry wanted it one way; FDA 11 interpreted this particular statutory provision another way. The 12 Quaker Oats case; it's cited in our brief. 13 The high court said look, the company might be right. 14 Their interpretation might be reasonable under the statute. But 15 that's not the issue. The issue is whether the agency made a 16 permissible choice. And if so, the agency must be sustained. 17 This cascading approach that has been advanced, Your 18 Honor — it's a red herring. FDA never even considered it. It's 19 not in the administrative record. This is something — you want 20 to talk about invention, Torpharm made it up in their brief. It 21 doesn't deserve any consideration. 22 The question is: Is the FDA's interpretation rational? 23 THE COURT: Well, that's the second question. 24 MR. RAUBICHECK: What's the first? 25 THE COURT: What should it be under Chevron?</p>

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<p style="text-align: right;">Page 46</p> <p>1 MR. RAUBICHECK: Well, under Chevron, yes. What should it 2 about under Chevron? 3 If the Court thinks that the statute is so clear that a 4 one-first-all-applicant approach is the only way to read the 5 statute, obviously, that's a matter of statutory construction for 6 the Court. 7 If, however, the Court believes that the statute is silent 8 or ambiguous on this point, then Chevron 2 comes into play, the 9 Mead case comes into play, the Barnhart case comes into play and 10 you must look at whether it's a permissible construction. 11 Now, one thing that I need to add, and I realize I'm 12 running out of time, but I should still address. Your Honor has 13 a motion. The motion effectively was argued by counsel so, it 14 seems to me, we ought to get the opportunity to speak. 15 What they have said is, in going through the surreply 16 briefs, this '449 patent that Alphapharm blocks Geneva on — they 17 say it doesn't really block Geneva because the notice of Geneva's 18 paragraph IV certification was sent to the wrong guy. That's 19 what they're saying. It wasn't sent to each owner of the patent. 20 I don't even know what the truth of that allegation is 21 because we don't have FDA's administrative record on what Geneva 22 filed and who they sent it to. The piece of paper that I put in 23 as Exhibit A to my supplemental declaration was Geneva's notice 24 letter on the '449 patent and other Paroxetine patents that 25 Geneva attached to its complaint against Alphapharm in an</p>	<p style="text-align: right;">Page 48</p> <p>1 MS. MAZZOCHI: Your Honor, if I may briefly respond on a few points. 2 First, with respect to the gabapentin situation, I would like to note that Judge Huvelle did, in fact, suggest that Apotex pursue a shared exclusivity claim in connection with the patents that were at issue. I further believe that under the first applicant approach in that case, had it been applied, we would have already triggered Purepac's exclusivity by now and could, in fact, have been on the market. As it stands right now under FDA's patent-by-patent approach, we are being kept off the market. 12 With respect to the statute itself, because we believe that -- we agree with Your Honor that if you start with the statute, in 355(j)(5)(B)(iv), the clause begins: "If the application contains a certification." And the certification is described in subclause (IV) of paragraph (2)(A)(vii). 17 Section (vii) states that the certification that is at issue is the one that includes the -- that -- with respect to each patent which claims the listed drug referred to in clause (i) is the one that is at issue. And when you look back at clause (i), that says "an abbreviated application for a new drug shall contain information to show that the conditions of use," et cetera, et cetera, "have been previously approved." 24 To Torpharm, that indicates that it is the application which matters.</p>
<p style="text-align: right;">Page 47</p> <p>1 infringement case that they sued against — against my client. 2 And it's still ongoing so it's a matter of public record. 3 We wanted to give the Court everything we had on the '449 4 patent. But that's not what really is important here. It's not 5 when the notice was sent to the patent owner and the ANDA holder. 6 The issue is: Did Alphapharm file its paragraph IV certification 7 with FDA before Geneva filed its paragraph IV certification with 8 FDA? The filing of the notice with FDA is what's at issue, not 9 when they sent the notice to the patent owner and ANDA holder. 10 What we're concerned about is: Who was first to file with 11 FDA? And it's clear on the record that Alphapharm beats Geneva 12 by about two years on that patent. So this, again, is a red 13 herring. 14 Now, counsel may argue, well, under -- you really have to 15 perfect the notice by filing — perfect the certification by 16 filing the notice, but that — they did perfect it. They did 17 send the notice. Now they want to attack the guys whom they sent 18 it to. 19 But that doesn't change the basic fact of when it was 20 filed with FDA. Filing a paragraph IV certification with FDA as 21 part of your ANDA is the critical line of demarcation here; it's 22 the critical standard. We beat them by two years. 23 That's all the court needs to know on that. 24 Thank you very much. 25 THE COURT: All right. Thank you.</p>	<p style="text-align: right;">Page 49</p> <p>1 And furthermore, going back to section (j)(5)(B)(iv), if we are looking at when the later application shall be made effective, because we are not dealing with a court decision here, but we are dealing with the date of commercial marketing, subclause (i) states that "the application shall be made effective not earlier than the date the secretary receives notice from the applicant under the previous application." 8 So that, too, indicates that we should be concerned with an application-by-application basis, not a patent-by-patent basis. And if we are dealing with an application issue, then this is Chevron step 1 and the Court is entitled to order FDA to not approve Alphapharm's ANDA. 13 And that is true — the Court doesn't even have to decide whether it wishes to adopt the one-first-applicant approach or whether Torpharm's cascading approach merits consideration in order to conclude that Alphapharm should not be entitled to secure final FDA approval under a shared exclusivity regime. 18 The other point I would like to address that FDA raised which — is the question of: Is having a shared exclusivity regime one that meets the policy goals of Hatch-Waxman? 21 We contend that under the facts here, it certainly does not. As we've seen here today, when you have the shared exclusivity regime, FDA may not even reveal who is the first filer of an ANDA that is entitled to an exclusivity period. If you're another generic, not even necessarily a first filer</p>

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<p>1 operating in the marketplace, you're not even going to know who 2 you should try to go after, perhaps, if you want to trigger their 3 exclusivity by getting an early court decision of your own on one 4 of the relevant patents.</p> <p>5 If you follow the one-first-applicant approach, there's 6 one applicant, a fixed number of patents and everyone in the 7 industry can figure out who they should be targeting if they want 8 to try to trigger their exclusivity period and which are the 9 patents that are at issue, because that is going to be readily 10 ascertainable and fixed in time.</p> <p>11 So if FDA's goal is to ensure that there are not -- that 12 an -- that a 180-day exclusivity period does, in fact, eventually 13 get triggered so that other people can get on the marketplace -- 14 other generics can get on the marketplace, having multiple 15 parties with exclusivity rights that the market can't even figure 16 out until -- you know, here we are five years after we filed our 17 first ANDA in 1998 and it wasn't until FDA's surreply brief that 18 we finally figured out who had exclusivity rights assigned to 19 whom -- you know, if you have a one-first-applicant approach, you 20 at least know who to go after with respect to --</p> <p>21 THE COURT: Well, if you're making a policy argument, how 22 can you argue that having four generic manufacturers with some 23 ability to put out on the market during an exclusive 180-day 24 period as opposed to just one doesn't advance the Hatch-Waxman 25 goals of getting as many generic -- cheaper generic drugs in the</p>	<p>1 out there and challenge patents will be markedly diminished. 2 THE COURT: Can I just ask you: It's a bit of a tangent, 3 but if the FDA shared exclusivity letter ruling was issued in 4 July, why did Torpharm wait until November 11th to sue? 5 MS. MAZZOCHI: We filed a citizen's petition with FDA 6 asking them to reconsider their ruling and we raised many of the 7 issues that we presented to the Court in its briefing. 8 We spoke with FDA, who had indicated that they were not 9 planning on issuing final approval to anyone -- we actually told 10 FDA that we would be suing earlier; they asked us to wait, on the 11 grounds that there was not going to be anyone receiving final 12 approval, so that they could give due consideration to our 13 citizen's petition, which they declined to take action on. And 14 the parties then entered into the present briefing schedule. 15 Thank you, Your Honor. 16 THE COURT: All right. Thank you. 17 I'm prepared to rule at this point. And I want to first 18 recite the facts that I think are most important in coming to a 19 decision here. 20 On December 29th of 1992, the FDA approved Glaxo's new 21 drug application for Paxil. And at the time, Glaxo submitted 22 information only on one patent which was listed in the Orange 23 Book, referred to as patent '723 for Paroxetine. 24 In March -- on March 31st of 1998, Torpharm submitted its 25 abbreviated new drug application for four dosage strengths of</p>
<p>1 market as fast as possible?</p> <p>2 MS. MAZZOCHI: I think there are two answers to that 3 response. First, I think that the sooner the 180-day exclusivity 4 period is triggered, the sooner everybody can get on the market. 5 It wouldn't even necessarily be limited to just four individuals. 6 Second of all, the more people who get put into the 7 exclusivity pie creates a disincentive to undertake the 8 litigation costs associated with being a first filer. To provide 9 a hypothetical, Apotex -- or Torpharm, rather, was the first to 10 certify to the '723 patent. Let's assume that there was only one 11 additional patent that was listed in the Orange Book and all of 12 the pending ANDA applicants certified to it on the same day. 13 Under FDA's current regime, all of those ANDA applicants 14 would be entitled to shared exclusivity, so even if Apotex would 15 have done everything right and gotten everything on file 16 immediately the day that a new patent was listed in the Orange 17 Book, what would have been a full exclusivity right for Torpharm 18 would now have been completely eliminated and would become no 19 exclusivity right at all. 20 And when you are dealing with major blockbuster drugs, 21 where the name brand drug companies fight extraordinarily hard 22 over five years -- and longer in our situation here with 23 Paroxetine Hydrochloride -- to try to maintain their own market 24 monopoly, I think that Apotex -- or Torpharm -- sorry, late in 25 the day -- Torpharm believes that the incentive to actually go</p>	<p>1 generic Paroxetine tablets. It included a paragraph IV 2 certification concerning the sole patent then listed in the 3 Orange Book in connection with Paxil -- that's P-A-X-I-L -- the 4 '723 patent. 5 Glaxo sued Torpharm for infringement soon thereafter, but 6 lost. Beginning in March of 1999, Glaxo began to list, within 30 7 days of their issuance by the Patent and Trademark Office, eight 8 additional patents in the Orange Book regarding Paxil. 9 And that triggered the obligation of existing and new 10 ANDA -- that's A-N-D-A -- applicants for generic Paroxetine -- 11 and that, I think, is P-A-R-O-X-E-T-I-N-E -- to file paragraph IV 12 certifications concerning the added patents. 13 Torpharm did so at various different times. 14 On October 6th, 1999, Alphapharm filed its ANDA for 15 Paroxetine tablets. Two other companies also filed Paroxetine 16 ANDAs and all three ANDAs included paragraph IV certifications 17 for the '723 patent among the other patent certifications. Some 18 of these three competitors filed certifications concerning some 19 of the eight new patents before Torpharm did. 20 On November 19th, 1999, Glaxo also listed late one patent, 21 the '449 patent, that had been issued 15 months earlier in August 22 of 1998. The existing applicants did not have to file paragraph 23 IV certifications concerning the late-filed '449 patent. While 24 some applicants did, Torpharm did not. 25 On July 30th, 2003, the FDA issued its final approval of</p>

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<p style="text-align: right;">Page 54</p> <p>1 Torpharm's ANDA and Torpharm began to sell its product on 2 September 8th, 2003, claiming an exclusive right to have no other 3 Paroxetine ANDA approved for 180 days; namely, until about 4 March 6th, 2004. 5 Also on July 30th, 2003, however, the FDA granted shared 6 exclusivity to three other Paroxetine ANDA applicants who had 7 filed paragraph IV certifications concerning some of Glaxo's 8 added nine patents before Torpharm did. 9 The FDA expects for Alphapharm's ANDA to be eligible for 10 final approval on January 3rd, 2004 and Alphapharm asserts its 11 right to sell its generic product on that date under the FDA's 12 shared exclusivity ruling. 13 Now, it seems to me that there is no genuine dispute about 14 these material facts and we can turn to whether either side is 15 entitled to a judgment as a matter of law. 16 Torpharm's first claim for relief asserts that the FDA 17 violated the Food, Drug and Cosmetics Act and the Administrative 18 Procedure Act by awarding shared exclusivity to the three other 19 ANDA applicants that certified first to subsequently listed 20 patents, but certified after Torpharm did to the '723 patent. 21 It seeks, among other things, a declaration of its right 22 to a fully exclusive 180-day marketing period and an injunction 23 against the FDA granting final approval of Alphapharm's or anyone 24 else's ANDA for immediate sale of Paroxetine tablets until after 25 that 180-day period expires.</p>	<p style="text-align: right;">Page 56</p> <p>1 This language may be thick, but in my judgment, it is not 2 ambiguous. Applying the facts here to the statutory language, 3 Torpharm filed its ANDA in 1998. It provided a paragraph IV 4 certification regarding the '723 patent. That was the only 5 patent listed in the Orange Book for this drug. At the time, 6 there were no other paragraph IV certifications needed to compete 7. Torpharm's paragraph IV certification requirements. 8 Torpharm was then a first filer for the drug product and a 9 first filer on the '723 patent. It was Glaxo, the brand name 10 manufacturer, that was then seeking to keep this generic 11 competitor off the market, that shortly thereafter began 12 submitting for listing in the Orange Book a series of additional 13 patents that the FDA says created the prospect of exclusivity 14 standoff. 15 It would be ironic if Congress meant to give the drug 16 innovators such power when its aim was to get more and cheaper 17 generics on the market faster. 18 Torpharm, therefore, responded to the incentive that 19 Congress crafted. It moved before all the others and filed to 20 take advantage of that exclusive 180-day marketing period for the 21 generic drug. 22 The other three filed after Torpharm did. All filed for 23 the same drug. All contained the same certifications regarding 24 the '723 patent that Torpharm filed. 25 Nothing in the language of the statute undermines</p>
<p style="text-align: right;">Page 55</p> <p>1 Under the APA, whether the FDA's letter ruling was not in 2 accordance with the law is subject to Chevron analysis. If the 3 language of the governing statute speaks unambiguously to the 4 issue in question, the only question is whether the agency has 5 given effect to Congress's clear command; if the statutory 6 language is ambiguous, then the Court must give deference to any 7 reasonable construction of the language by the enforcing agency. 8 In this case, there are two principal statutory provisions 9 at issue. The first defines what a paragraph IV certification 10 must be. It is, quote: "A certification, in the opinion of the 11 applicant with respect to each patent which claims the listed 12 drug for which the applicant is seeking approval, that such 13 patent will not be infringed by the manufacture, use or sale of 14 the new drug for which the application is submitted." That 15 language is found at 21 U.S. Code section 355(j)(2)(A)(vii)(IV). 16 The second statutory provision is found at 21 U.S. Code 17 355(j)(5)(B)(iv), which provides a 180-day exclusivity for the 18 first applicant. The pertinent language says about subsequent 19 applications that: "If the application contains a certification 20 and is for a drug for which a previous application has been 21 submitted under this subsection containing such a certification, 22 the application shall be made effective not earlier than 180 days 23 after the date the secretary receives notice from the applicant 24 under the previous application of first commercial marketing of 25 the drug under the previous application."</p>	<p style="text-align: right;">Page 57</p> <p>1 Torpharm's status as the previous applicant, entitled to the 2 exclusivity whenever the innovator lists new patents before the 3 first ANDA is approved, that subsequent filers might certify on 4 before the previous applicant does. 5 The plain language of the statute grants one first 6 applicant exclusivity in marketing the new generic drug. It 7 seems from the FDA's opposition brief that the FDA may have first 8 abandoned the 1999 one-first-applicant proposed regulation 9 because of negative comments received, not because the proposal 10 was not faithful to the command of the statute. 11 But nevertheless, the FDA next abandoned the 12 one-first-applicant approach in 2001, based upon its reading of 13 the language not of the statute, but of its own implementing 14 regulation. That reading created the principle that eligibility 15 for exclusivity is based upon the particular patent at issue and 16 not the drug product as a whole. 17 And I'm not even sure that the language of its own 18 regulation mandates that principle, particularly if you integrate 19 it with the facts here: 20 If you do that, the regulations would read: If Alpha's 21 abbreviated new drug application contains a certification that 22 the '723 patent will not be infringed and the application is for 23 a generic copy of the same Paroxetine drug for which Torpharm's 24 substantially completed abbreviated new drug application was 25 previously submitted containing a certification that the '723</p>

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<p style="text-align: right;">Page 58</p> <p>1 patent would not be infringed, approval of Alphapharm's 2 abbreviated new drug application will be made effective no sooner 3 than 180 days from the date Torpharm first commences commercial 4 marking of its Paroxetine tablets."</p> <p>5 In any event, even giving due deference to the agency's 6 interpretation of its own regulation, as I must, what is key is 7 whether the FDA has given effect to the clear command of the 8 statute, not its own regulation.</p> <p>9 All of the regulatory discussion about a patent-based 10 approach and exclusivity standoff seems to have sprung from the 11 regulators being enmeshed in the consequences of their 12 interpretation of the regulation, rather than the plain language 13 of the statute.</p> <p>14 I reach my conclusion wholly independent of the fact that 15 Congress last month amended the statute to make explicit the 16 product-based approach for the 180-day exclusivity period.</p> <p>17 The FDA argues in its opposition brief that the fact that 18 the amendment added new protections from the potential abuses of 19 a product-based system confirms that the FDA had appropriately 20 construed the previous version of the statute.</p> <p>21 It might be quite the contrary. It may suggest that the 22 FDA previously got it wrong, although the FDA's concerns about a 23 product-based system did warrant some statutory fixing.</p> <p>24 In conclusion then, Torpharm is entitled to a declaration 25 that the FDA acted contrary to the plain language of Section</p>	<p style="text-align: right;">Page 60</p> <p>1 very least, by Monday.</p> <p>2 THE COURT: All right. Let me ask that you do that.</p> <p>3 And let me ask opposing counsel to look carefully at the 4 draft and provide any feedback that you think might be warranted 5 to the drafting counsel so that that can be filed as soon as 6 possible to have a written memorialization of my oral ruling.</p> <p>7 All right. Thank you very much, counsel, and good 8 arguments. I appreciate hearing from all of you. Thank you for 9 coming in.</p> <p>10 You may be excused.</p> <p>11 (Proceedings adjourned at 4:06 p.m.)</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18 I, Scott L. Wallace, RDR-CRR, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.</p> <p>19</p> <p>20</p> <p>21 Scott L. Wallace, RDR, CRR Official Court Reporter</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 59</p> <p>1 355(j)(5)(B)(iv) by awarding it shared exclusivity with three 2 other subsequent ANDA applicants rather than a sole exclusive 3 180-day marketing period for its generic Paroxetine tablets.</p> <p>4 Torpharm is also entitled to an injunction against the FDA 5 that preserves the status quo by barring the FDA from granting 6 final approval of Alphapharm's or anyone else's ANDA for 7 immediate sale of Paroxetine tablets until after Torpharm's 8 180-day exclusive period expires.</p> <p>9 I will enter judgment in favor of Torpharm on the first 10 claim of its amended complaint.</p> <p>11 Because the relief I am granting on the first claim of its 12 amended complaint is, in effect, equal to or broader than the 13 relief sought on the second and third claims of the amended 14 complaint, I will dismiss those claims as moot.</p> <p>15 This order is effective immediately, but I will ask 16 Torpharm to draft a final written order consistent with this 17 ruling and share it with opposing counsel for comment and joint 18 revision, if any revision is needed, and then file it with the 19 Court so there can be a written version of this oral order.</p> <p>20 Let me ask counsel for Torpharm how quickly you think you 21 can do that?</p> <p>22 MS. MAZZOCHI: We'll do it tonight.</p> <p>23 THE COURT: I can't hear you. Come up to the mike.</p> <p>24 MS. MAZZOCHI: I apologize. We will try to circulate a 25 draft to opposing counsel by the end of the day today or, at the</p>	

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